MAY 0 2 2002

510(k) Summary K020930

Applicant's Name and Address: Menicon Co., Ltd.
21-19, Aoi 3-Chome
Naka-ku, Nagoya 460-0006
Japan

Contact Person: Tohru Kawaguchi
Phone 011 81 (52) 935-1676
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Summary Prepared March 2002

Trade Name:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Classification Name:

rigid gas permeable contact lens solution

Common/Usual Name

periodic cleaner; disinfecting solution

Predicate Device:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses (K002140).

Device Description:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses consists of two solutions, Progent A and Progent B, which are mixed together when used. They are packaged separately in natural low density polyethylene (USP classification :VI) ampoules, type "Bottle Pack", containing 5.5 ml of solution, (5 ml being usable). Each package consists of 7 pairs of ampoules.

Progent A contains sodium hypochlorite and sodium carbonate; Progent B contains potassium bromide and sodium carbonate. Rigid Gas Permeable Contact Lenses are placed into the lens holder cap of the cleaning vial (SP Vial). Progent A, then Progent B are poured into the case receptacle, then the lenses are soaked in the Progent mixture for 30 minutes.

Indication for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans, disinfects and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

Substantial Equivalence:

The claim of substantial equivalence to Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is based on the fact that the product is the same formulation. Only the indications and directions for use have been modified.

The applicant performed non-clinical stability, toxicology and microbiology testing which supports the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 02 2002

Menicon Co., Ltd.
c/o Beverly D. Venuti, Ph.D., RAC.
Foresight Regulatory Strategies, Inc.
269A Ballardvale St.
Wilmington, MA 01887

Re: K020930
Trade/Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenes
Regulation Number: 21 CFR 886.5918
Regulation Name: RGP Contact Lens Solution
Regulatory Class: Class II
Product Code: MRC
Dated: March 20, 2002
Received: March 22, 2002

Dear Dr. Venuti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K020930

Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans, disinfects and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

This product is for professional in-office use only.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W C Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020930

Prescription Use X
(Per 21 CFR 80.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)